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1. Your reference — WMO/P200507 — Case 2

2. Patent application number *(The Patent Office will fill in this part)* — 28 OCT 2003 — 0325277.2

3. Full name, address and postcode of the or of each applicant *(underline all surnames)* — Xiros PLC, 30 Blenheim Terrace, Leeds, LS2 9HD

   Patents ADP number *(if you know it)* — 08008567001

   If the applicant is a corporate body, give the country/state of its incorporation

4. Title of the invention — Surgical instruments for use in the implantation of tissue repair kit

5. Name of your agent *(if you have one)* — Urquhart-Dykes & Lord

   "Address for service" in the United Kingdom to which all correspondence should be sent *(including the postcode)* — Tower North Central
   Merrion Way
   Leeds LS2 8PA
   United Kingdom

   Patents ADP number *(if you know it)* — 1644004

6. If you are declaring priority from one or more earlier patent applications, give the country and the date of filing of the or of each of these earlier applications and *(if you know it)* the or each application number

Country	Priority application number *(if you know it)*	Date of filing *(day / month / year)*

7. If this application is divided or otherwise derived from an earlier UK application, give the number and the filing date of the earlier application

Number of earlier application	Date of filing *(day / month / year)*

8. Is a statement of inventorship and of right to grant of a patent required in support of this request? *(Answer 'Yes' if*
   a) any applicant named in part 3 is not an inventor, or
   b) there is an inventor who is not named as an applicant, or
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   See note (d)) — YES

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Continuation sheets of this form	
Description	8
Claim(s)	
Abstract	
Drawing(s)	10

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Statement of inventorship and right to grant of a patent *(Patents Form 7/77)*	
Request for preliminary examination and search *(Patents Form 9/77)*	
Request for substantive examination *(Patents Form 10/77)*	
Any other documents *(please specify)*	

11. I/We request the grant of a patent on the basis of this application.

Signature

Date 28-10-03

12. Name and daytime telephone number of person to contact in the United Kingdom

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CASE 2

SURGICAL INSTRUMENTS FOR USE IN THE IMPLANTATION OF TISSUE REPAIR KIT

This invention relates generally to surgical instruments for use in preparing a bone site with damaged tissue, and for implantation of a tissue repair kit on the prepared bone site, and which includes bone sites on animals and humans.

The invention has been developed primarily, though not exclusively, in connection with the repair of damaged cartilage and the repair of cartilage defects in synovial human or animal joints, and in particular to provide further improvement in the art over the disclosure in WO01/39694. However, it should be understood that the invention has wider application to the repair of damaged tissue in other sites in a human or animal body.

According to the invention there is provided an introducer tool for implanting a repair kit on a prepared bone site from which damaged tissue has been removed, and around which a groove into the bone has been formed, said kit comprising a bio-compatible pad to fit on the prepared bone site, and an overlying cover sheet to fit in the groove, and in which the tool comprises:

an introducer cylinder having a hollow circular driving head at one end for introducing an outer portion of the cover sheet into the groove;

a plunger relatively slidable within the cylinder and having a delivery end onto which the cover sheet can be placed, prior to entry of the plunger into the cylinder, so as to move a main portion of the cover sheet towards the bone site with the outer portion of the cover sheet trailing behind the main portion; and

a pad-receiving recess defined between the delivery end of the plunger and the inner wall of the cylinder when the cylinder and the plunger are relatively adjusted to a pad-implantation position, so that a pad can be introduced into the recess so as to overlie the main portion of the cover sheet:

in which relative withdrawal of the driving head of the cylinder, followed by relative advancing movement, allows the driving head to engage the trailing portion of the cover sheet and to introduce the trailing portion into the groove while the pad engages the bone site and thereby to anchor the pad in position.

By way of background to the invention, there will firstly be described a tissue repair kit, and method of implantation, which are disclosed in more detail in International Publication number WO01/39694, to which reference is drawn.

Figures 1 to 3 of WO01/39694 illustrate the preparation of a bone site having damaged issue, and the implantation of a repair kit on the prepared site.

Referring therefore to Figures 1 to 3, there is illustrated part of a knee joint (1) including bone (3) overlaid with cartilage (5). An annular space or groove (7) is formed which extends through the cartilage and into the bone, terminating within the bone, at a level that is a multiple of cartilage depth, for example, 4 or 5 times the depth of the cartilage.

Removal of the damaged cartilage from the area of bone defined by the groove (7) results in a space into which is located a small piece or pad of bio-compatible material (9). Pad (9) is shaped and dimensioned to occupy substantially the entire space previously occupied by cartilage, and the depth of pad (9) corresponds approximately to that of the surrounding cartilage (5).

Figure 2 shows use of a reamer (15) having a toothed edge (17) at one end, and provided with a thin steel rod (19) and near one end there is located a cylinder (21) of external diameter such as to be a snug fit within reamer (15). Adjacent cylinder (21), steel rod (19) has a pointed end (23) enabling rod (19) and its associated cylinder (21), to act as a guide for the reamer (15). In use, the pointed end (23) is located at the centre of the site which includes the damaged cartilage tissue. Light pressure is applied to the steel rod. Reamer (15), located around steel rod (19) and cylinder (21), while being rotated, is then subjected to relatively heavy pressure to cut an annual groove which extends though the cartilage and into the bone, as illustrated in Figure (1).

Once the material (9) has been positioned at the site from which damaged tissue has been removed, a piece of thin netting/mesh or tissue (11) (forming a cover layer) is then located in the position illustrated in Figure 1. Mesh 11 extends over the pad (9) and into the annular groove (7) into which it is a push-fit.

Preferred embodiments of introducer tool and reamer tool according to the invention will now be described in more detail with reference to Figures 4 to 10 of the accompanying drawings, in which:

Figure 4a is a sectional view of an assembled reamer and spring loaded centraliser for use in removing damaged tissue from a bone site;

Figure 4b is a perspective view of the reamer;

Figure 5 is a perspective view of a cartilage cutter for use with the reamer;

Figure 6 is an exploded view of the operating (cutting end) of a residual cartilage removal tool;

Figure 7a is a perspective view of an assembly of an introducer/delivery instrument for implanting the repair kit comprising pad and retaining cover sheet;

Figures 7b, c and d are illustrations of the component parts of the tools shown in Figure 7a;

Figure 8 shows successive views of loading the repair kit into the delivery device/introducer tool;

Figure 9 shows successive stages in the implantation of the repair kit on the prepared bone site; and

Figure 10 illustrates the loading of a number of bio-compatible pads in a delivery instrument.

Instruments for preparing the repair site prior to implanting the device

This is an assembly consisting of stationary and rotating concentric components. The first is a centralising device with a cylindrical section that has at one of its ends a sharp point that pierces the bone and defines the centre of the circle delineating the defect site. This centralising device is contained within a reaming device that is used to make the annular groove surrounding the repair site, said reamer to be of wall thickness similar to the annual groove it is to generate in the bone at the repair site. At one end the reamer is adapted to connect to a power drill, the other end has sharp teeth that remove bone debris as it penetrates the bone to a depth according to a mark on the body of the reamer. At least one channel is cut at the end of the reamer containing the teeth to allow the debris to escape away from the groove, said channels are some 10-15 mm long and can be either parallel or inclined to the long axis of the reamer. The centraliser is spring loaded within the reamer and the spring-loaded centraliser and reamer are supplied as separate entities to be assembled before use or preferably as an assembly comprising both and ready for use. The advantage of the spring-loaded centraliser over the one described in the disclosure in WO01/39694 is that the spring-loaded centraliser allows the surgeon to use one hand, rather than both, for simultaneously maintaining the centraliser engaged with the bone under the pressure of the spring while cutting the annular groove with the reamer.

Figure 4a illustrates the assembled spring-loaded centraliser within the reamer, and Figure 4b illustrates the reamer alone with the cut channels at its cutting edge.

In addition to the reamer and centraliser is supplied a cartilage cutter in the form of a cylindrical component (illustrated in figure 5) that is used in conjunction with the reamer and spring-loaded centraliser assembly and when used it surrounds the reamer closely, and has a sharp cutting circular edge at its end near the cartilage surface and such cutter is used to effect a circular cut in the cartilage to it full depth. This is done by pressing the cutter against the cartilage surface while rotating the cutter around the body of the reamer. The cartilage cutting is performed after engaging the centraliser into the bone at the repair site, but before making

the groove into the bone with the reamer. Thus while the centraliser is in place the cartilage is first cut with the cutter which is then held with its cutting edge in its final position at the cartilage/bone interface and the reamer is then rotated to make the groove to the required depth. Keeping the cutter at the cartilage bone interface protects the edge of the sound cartilage surrounding the repair site from damage were this to come in contact with the rotating surface of the reamer. The advantage of this instrumentation assembly for preparing the annular groove is that the surgeon can use one hand to engage the centraliser and later to operate the drill, while with the other hand he/she can operate the cartilage cutter and maintain it in its position at the cartilage bone interface, while operating the power drill to make the groove in the bone.

Instruments for the removal of residual cartilage in the repair site

Included also is a guard to protect the sound cartilage edge delineating the repair site while removing the residual cartilage from the site, the guard which is a single component in the form of a thin cylindrical be placed within the annular groove whilst removing the residue of cartilage with a rotating tool the end of which is machined flat on either side leaving a central portion in the form of a dove tail with two cutting edges as shown in Figure 6. The advantage of this cutting edge configuration is that it can reach to the edge of cartilage close to the guard within the defect site and also that the tool can be effectively used rotated in one direction or the reverse.

Instruments for implanting devices for cartilage repair

The following firstly describes improved instruments for the process of implanting the device described in the disclosure in WO01/39694 in which one of the configurations used a device for cartilage repair comprising a pad and cover sheet for retaining the pad in the annular groove. The instruments described in what follows comprise a delivery instrument for the implantation of the device through the necessarily small incisions made to access the repair site and to facilitate loading the delivery instrument.

The delivery instrument consists of a flat-ended circular plunger placed and slideable within another cylindrical thin walled component. Thickness of the wall of the outer component and its diameter are such that it can push the retaining cover sheet within the annular groove as the

pusher component described in the disclosure in WO01/39694, said outer component has a circular flange at one end that is of a diameter substantially equal to or slightly larger than the diameter of the cover sheet. The plunger protrudes beyond this flange by a length that facilitates operation, while its other end stops inside some 5-7 mm distance from the end of the outer component. The plunger may or may not have a thin central pin protruding from its end contained within the outer thin walled component and has some means of retaining it in that position, such as for example a horizontal through pin that prevents it from sliding further into the outer component when introduced through it via its flanged end. The assembled delivery instrument is shown in Figure 7a and its constituent components in Figure 7b, 7c, and 7d.

The method of using this delivery instrument is as follows:

The device is disassembled keeping the through pin attached to the plunger. One or two of the retaining cover sheets are placed onto the flange, concentrically. The Plunger is then pushed onto the cover sheet(s) through the flange hole and is prevented from sliding within the thin walled outer component beyond the limit set by the through pin. The cover sheets are thus dragged into the thin walled outer component and kept furled around the plunder pierced by the pin in its flat end, where a pin is provided. Pads of the required number for the repair site are then placed within the free end of the outer component and pushed to lie flat against the flat end of the plunger. If the latter has a central pin the latter will pierce the pad(s) centrally. The method of loading the delivery instrument described above is shown in Figure 8.

To implant the device into an already prepared site with the annular groove made and the residual cartilage removed, having loaded the device (i.e. pads and cover sheets) into the delivery instrument as described above, the delivery instrument is introduced into the annular groove and pushed into it to the limit set by the space between the pads within and the edge of the instrument. The outer component is kept at that position within the annular groove maintaining pressure on the free end of the plunger so as to engage the pin in the flat end of the plunger into the bone at the centre of the repair site. The horizontal retaining pin is withdrawn from the plunger and the outer component is slid around the plunger away from the annular groove until it releases the curled cover sheets captive within it, allowing the cover sheets to unfurl. While maintaining pressure on the plunger end thus keeping the pads located

centrally within the repair site the cover sheets are pushed into the annular groove with the outer cylindrical component in the same way as the pusher component is used as described in the disclosure in WO01/39694. The pin in the flat-ended plunger would maintain the central location of the pads within the repair site while pushing the cover sheets with the outer thin walled component. The steps for implantation of the repair implant are illustrated in Figure 9.

Another component, which facilitates the loading of pads in the delivery instrument, is a rectangular block, which has a number of wells prepared to the same configuration and dimensions of a repair site. The block can be supplied with the wells already charged with one or more pads stacked in the different wells, such pads can be picked up by the delivery instrument as the latter is introduced into the annular groove within any well. The pads would simply adhere within the inside of the delivery instrument. The bock and method of using it are shown in Figure 10. The upper surface of a well may have a central hole into which the pin in the flat ended plunger of the delivery instrument may pass piercing a pad centrally as it is picked from a well within the said block.

Accordingly, preferred embodiments of reamer tool and introducer tool according to the invention, as described above with reference to Figures 4 to 10, are improved tools, giving easier preparation of a bone site having damaged tissue, and subsequent implantation of a tissue repair kit, formed of a bio-compatible pad and overlying cover sheet.

In particular, the introducer tool serves to implant a repair kit on a prepared bone site from which damaged tissue has been removed, and about which a groove into the bone has been formed, in which the kit comprises a bio-compatible pad to fit on the prepared bone site, and an overlying cover sheet to fit in the groove, to anchor the pad in position.

The tool comprises an introducer cylinder having a hollow circular driving head at one end for introducing an outer portion of the cover sheet into the groove.

A plunger is relatively slidable within the cylinder and has a delivery end onto which the cover sheet can be placed, prior to entry of the plunger into the cylinder, and so as to move a main

portion of the cover sheet towards the bone site with the outer portion of the cover sheet trailing behind the main portion.

A pad-receiving recess is defined between the delivery end of the plunger, and the inner wall of the cylinder when the cylinder and the plunger are relatively adjusted to a pad-implantation position, so that a pad can be introduced into the recess so as to overlie the main portion of the cover sheet.

Subsequently, relative withdrawal of the driving head of the cylinder, followed by relative advancing movement, allows the driving head to engage the trailing portion of the cover sheet and to introduce the trailing portion into the groove while the pad engages the bone site and thereby to anchor the pad in position.

Case 2.

~~1/9~~

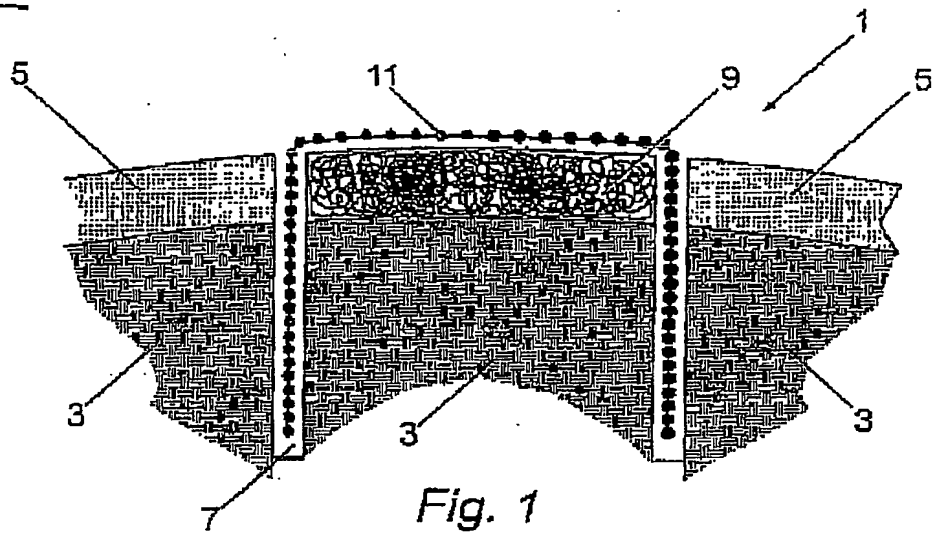

Fig. 1

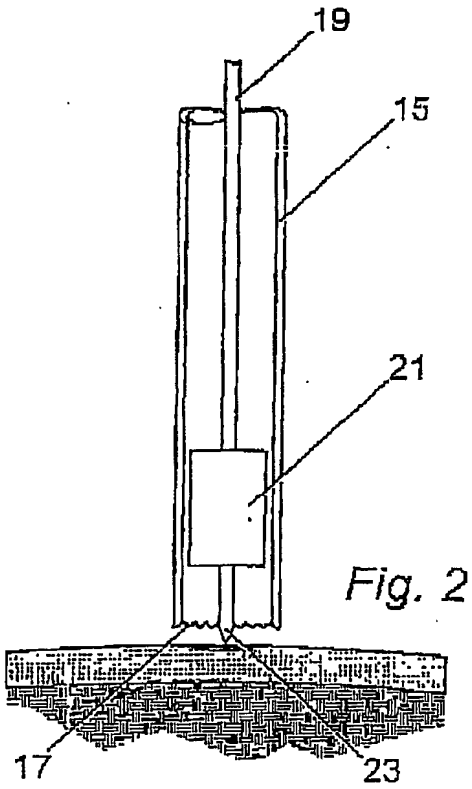

Fig. 2

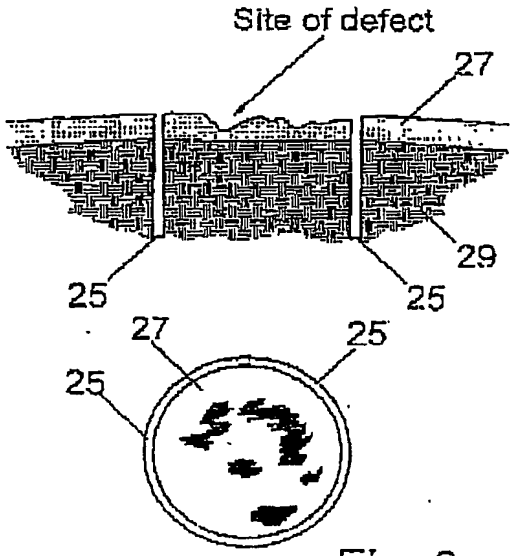

Fig. 3

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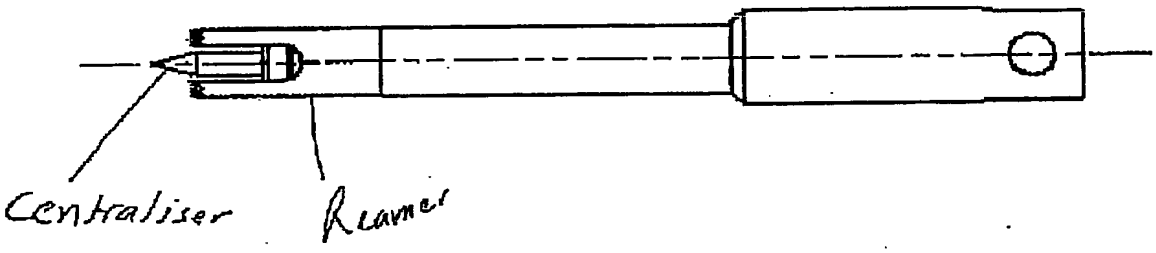

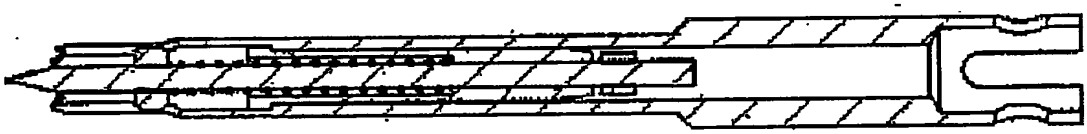

Section through assembled reamer and spring loaded centraliser

~~Figure 4a~~

Figure 4a

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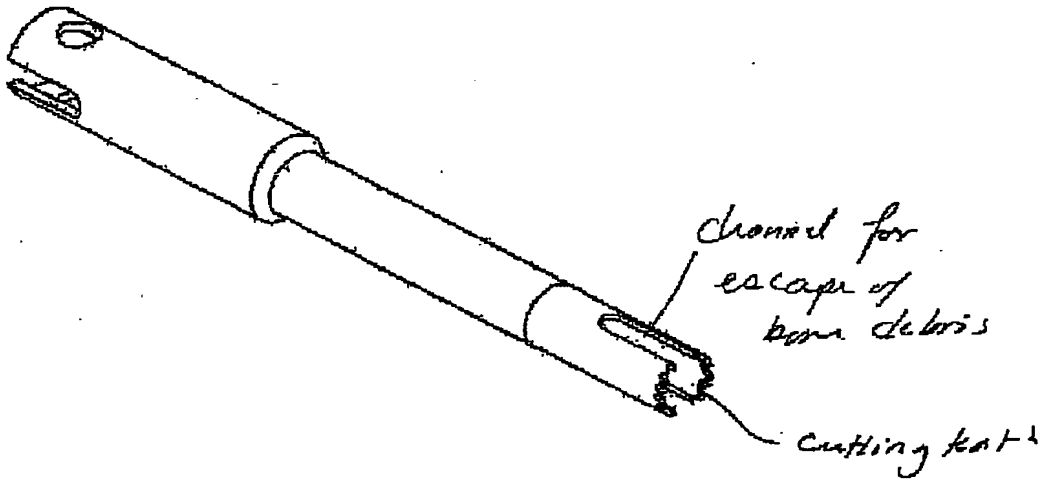
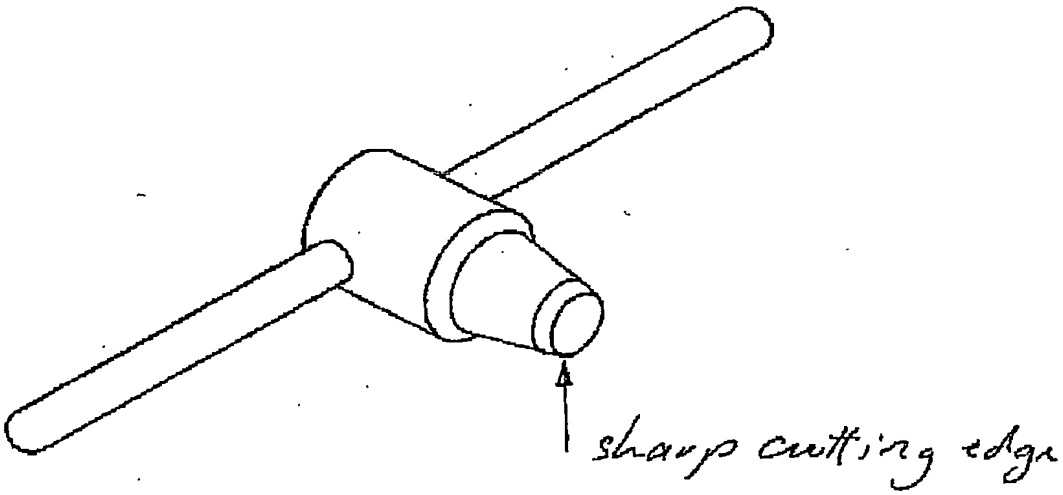


Reamer

~~Figure 4b~~

Figure 4b

4/10

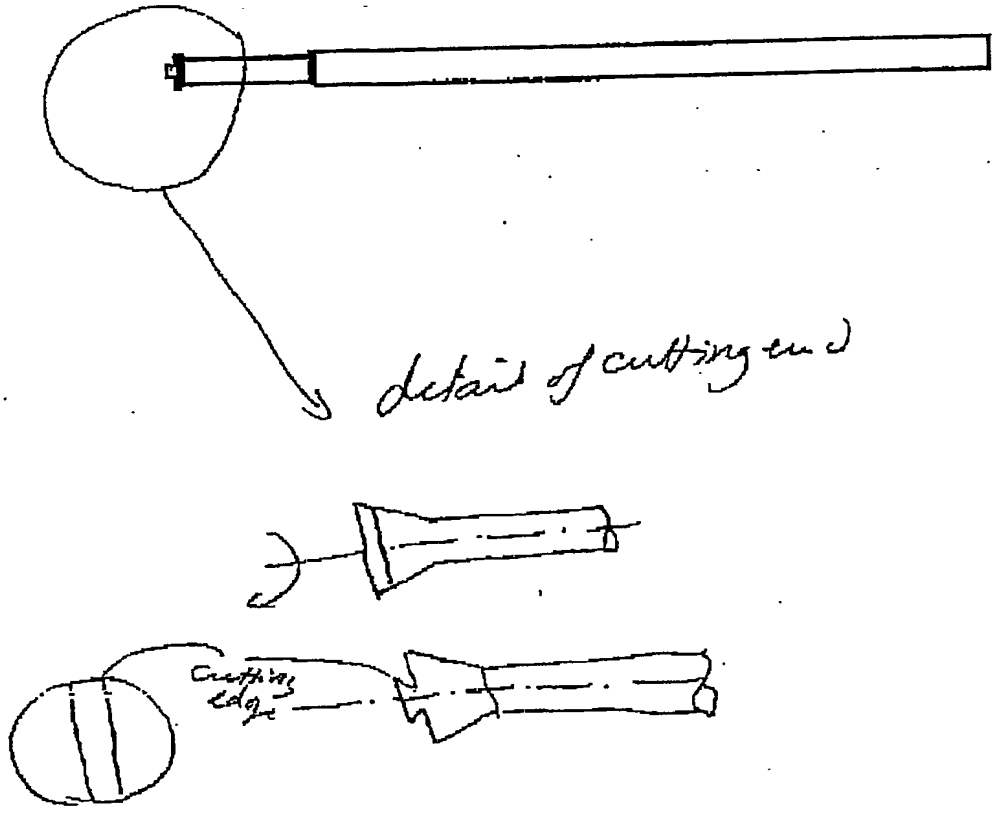


Cartilage cutter

~~Figure 2~~

FIG. 5

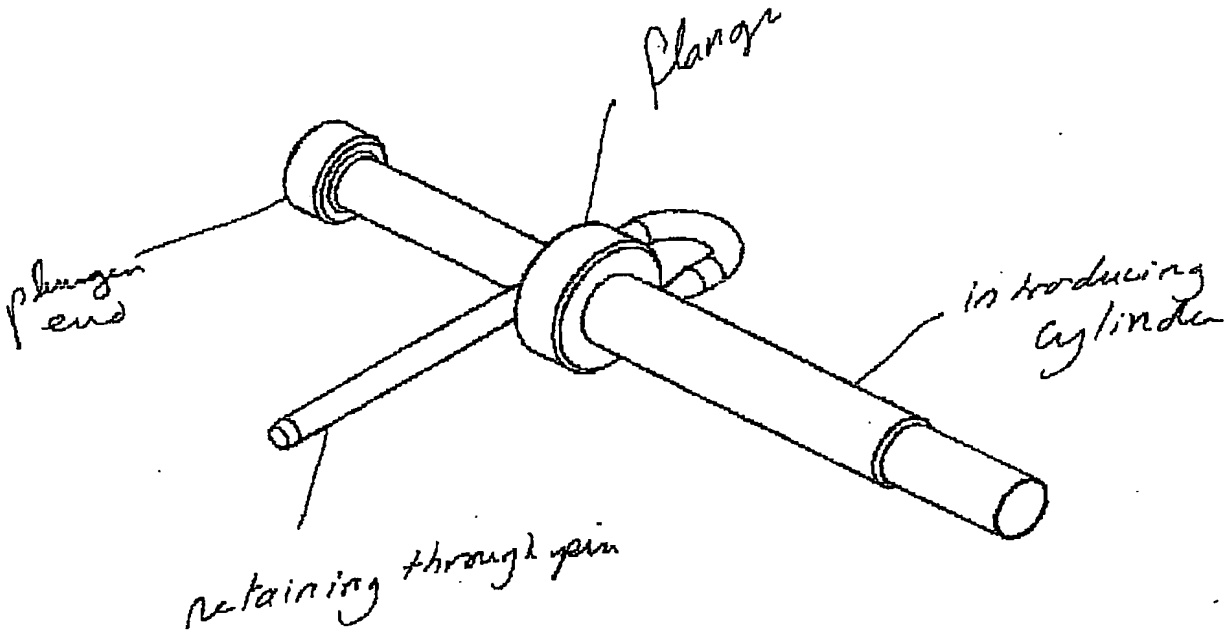
5/10



Residual Cartilage removing tool

Figure 6.

6/10



Assembly of introducing/delivery instrument

Figure ~~13a to a~~ 7a

7/10

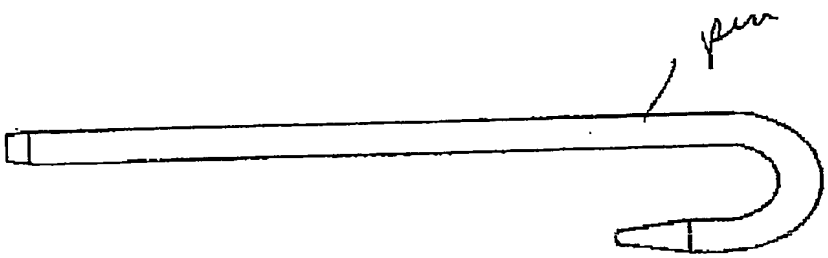


Fig ~~12b~~ ~~10b~~ 7b

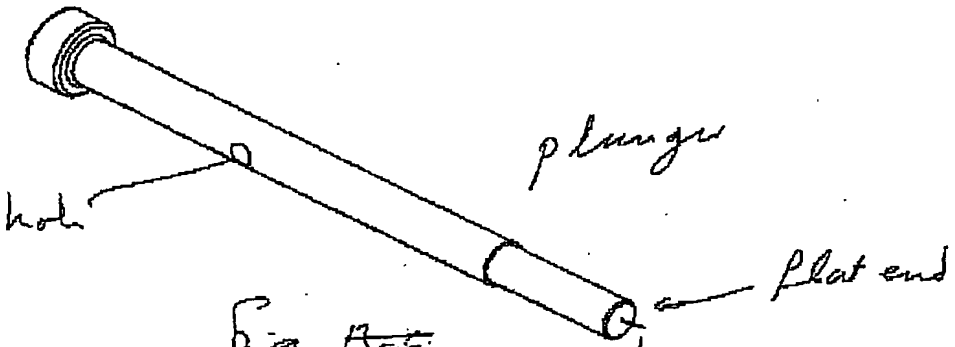


Fig ~~11c~~ ~~10c~~ 7c

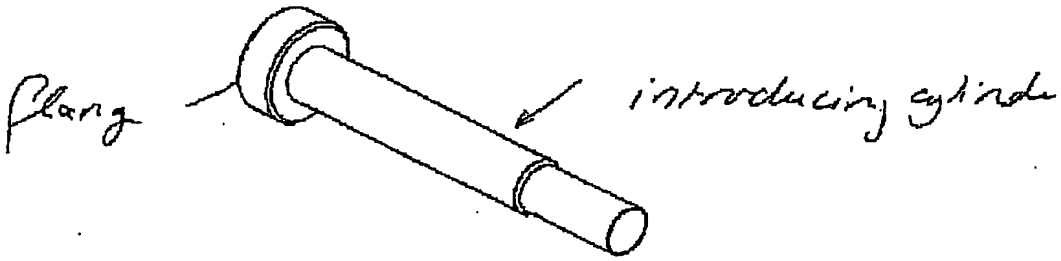


Fig ~~11d~~ ~~10d~~ 7d

8/10

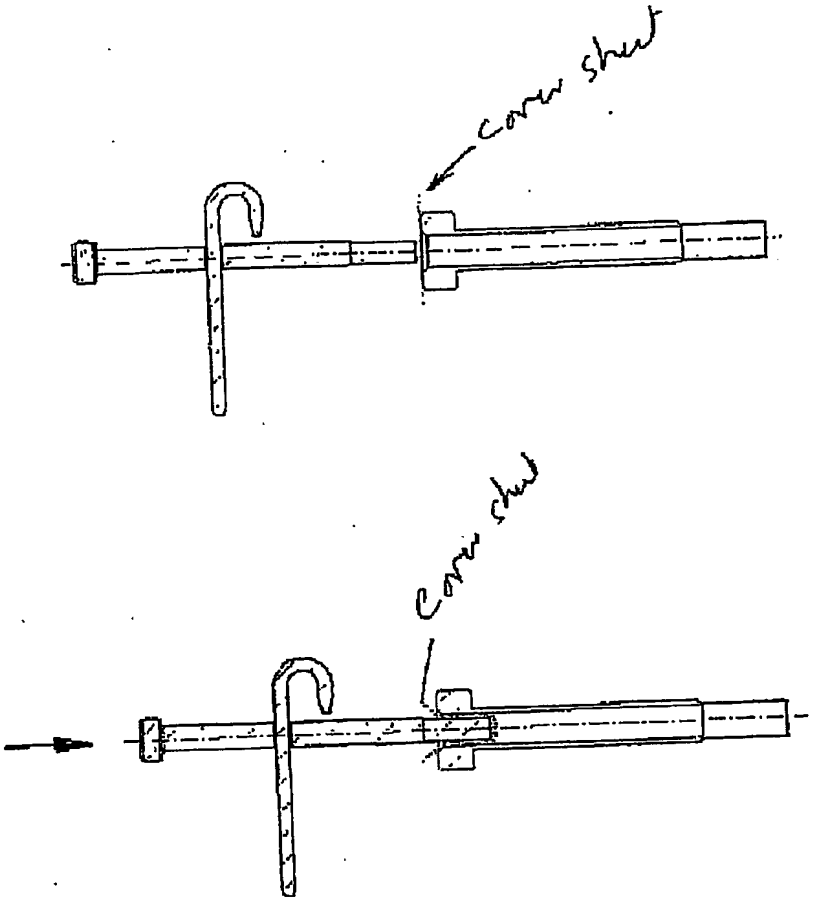


Figure ~~14~~ 8.

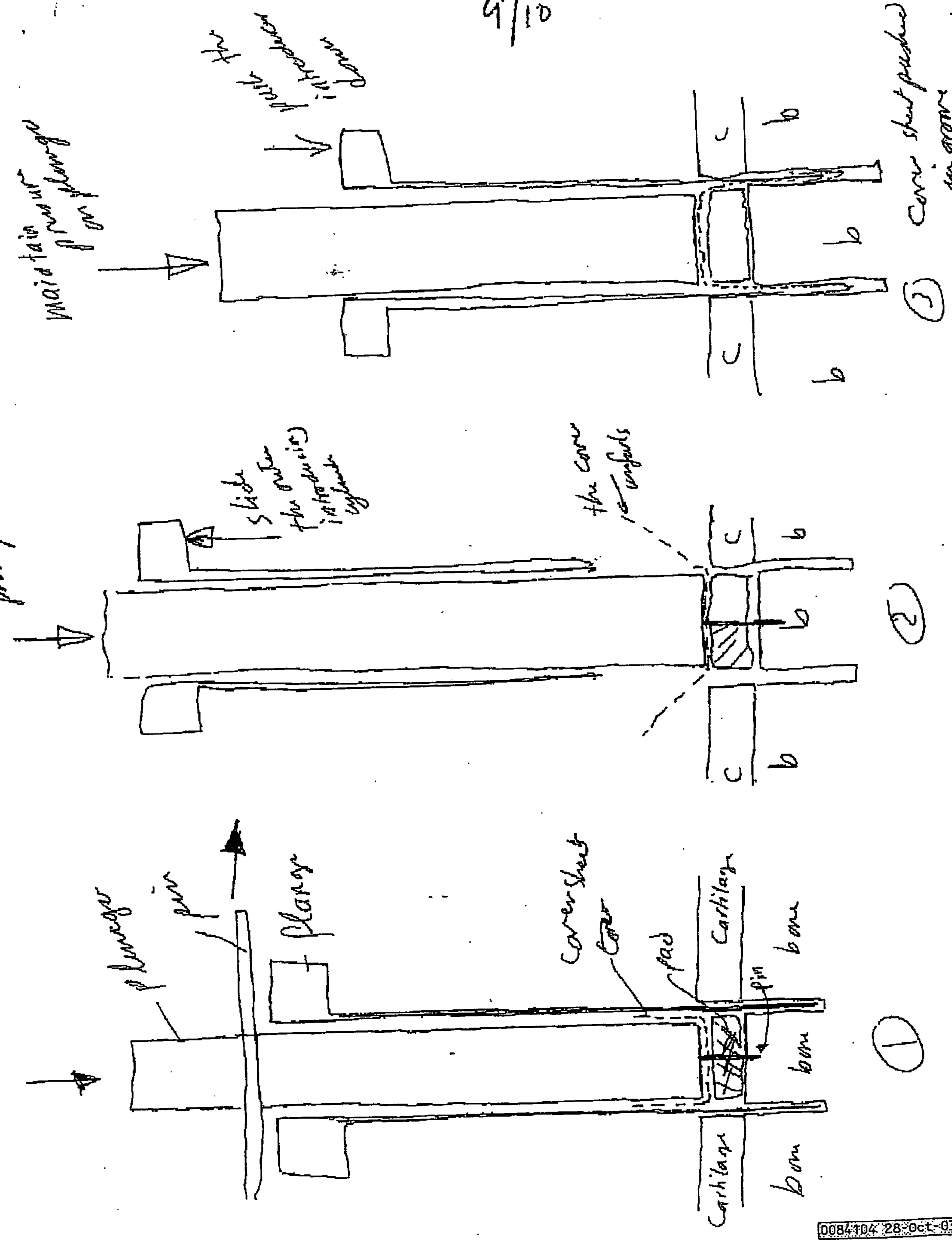


Figure 9

10/10

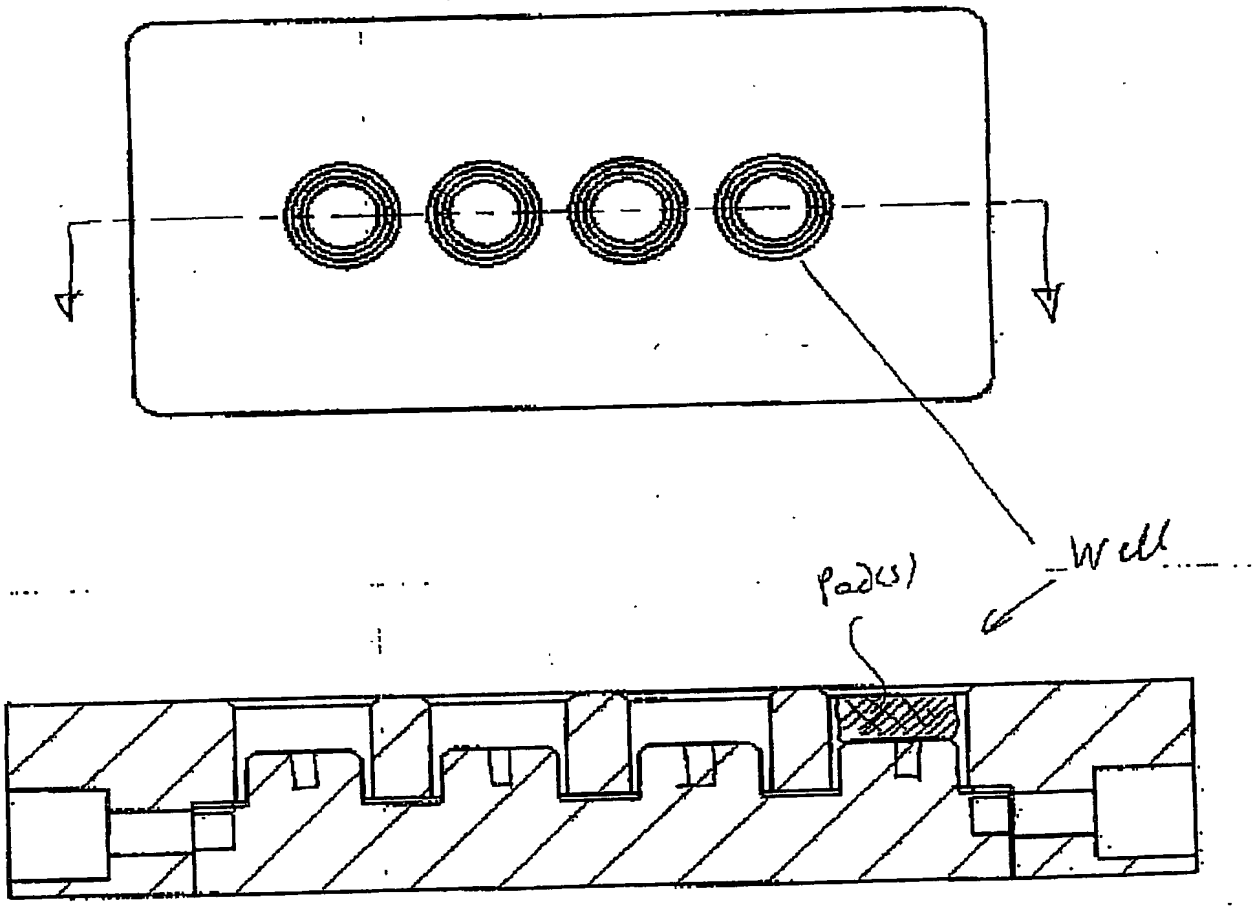


Figure 6 B 10.